



Press Release, February 6, 2023

Diamyd Medical receives patent protection in the US and Japan for GABA formulation Remygen®

The US Patent and Trademark Office (USPTO) and the Japanese Patent Office have informed Diamyd Medical that they will grant the patent for the Company's oral formulation of the GABA-based study drug Remygen®. Remygen® is currently in Phase 2 development through the ReGenerate-1 trial in individuals with long-term Type 1 Diabetes. Results are expected later this quarter.

“The ongoing phase 2 trial ReGenerate-1 will guide us on how to move forward with Remygen”, says Ulf Hannelius, CEO of Diamyd Medical. “Patent protection for the formulation is important for all possible routes forward, especially for commercially important geographies such as the US and Japan”.

In addition to the Remygen® formulation patent, Diamyd Medical holds an exclusive license from the University of California, Los Angeles (UCLA), for treating diabetes and other inflammatory disorders with GABA alone and in certain combinations including GABA receptor modulators and antigen-specific immunotherapies. Diamyd Medical has also filed patents on GABA's therapeutic effect on the hormonal counter-regulatory response to low blood sugar levels.

About Remygen®

Remygen® is Diamyd Medical's proprietary formulation of GABA, a key cell signalling molecule in the islets of Langerhans found in the pancreas. GABA has been shown to affect the secretion of insulin and glucagon both in healthy volunteers and in patients. Preclinical studies have shown strong indications that GABA stimulates the growth and function of the insulin and glucagon producing cells in the pancreas. Preclinical studies have also shown that GABA receptor modulating agents such as Alprazolam may increase the positive effect of GABA on the insulin producing cells.

About ReGenerate-1

ReGenerate-1 is an open-label, investigator initiated clinical trial involving a total of 35 patients aged 18-50 who have had type 1 diabetes for longer than five years with low to non-existing residual insulin production. The trial is conducted at Uppsala University Hospital with Professor Per-Ola Carlsson as Principal Investigator. The trial consists of two parts; an initial safety and dose escalation part comprising six patients, and the main trial, which comprises 35 patients who will be followed up to nine months depending on the dose group to which they belong. The main purpose is to evaluate the safety of Remygen® and the combination of Remygen® and the GABA receptor-modulating substance Alprazolam. The trial will also examine whether Remygen® alone and in combination with Alprazolam can have a positive effect on the hormonal counter-regulatory response to low blood sugar and on the restoration of beta cell function, potentially allowing in the long run a patient to regain insulin producing capacity.

The results from the dose-escalation part of ReGenerate-1 are published in the article “GABA induces a hormonal counter-regulatory response in subjects with long-standing type 1 diabetes” that can be accessed at <https://drc.bmj.com/content/9/1/e002442>

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for Type 1 Diabetes. Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruiting patients with recent-onset Type 1 Diabetes in eight European countries. Significant results have previously been shown in a large genetically predefined patient group in a large-scale meta-analysis as well as in the Company's European Phase IIb trial DIAGNODE-2, where the Diamyd® was administered directly into a lymph node in children and young adults with recently diagnosed Type 1 Diabetes. A biomanufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the antigen-specific immunotherapy Diamyd®. Diamyd Medical also develops the GABA-based

investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. An investigator-initiated Remygen® trial in individuals living with Type 1 Diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB as well as in the artificial intelligence company MainlyAI AB.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

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